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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,440	08/14/2003	Eli Wallace	ARR002	2454
37802	7590	03/10/2006	EXAMINER	
HOGAN & HARTSON LLP ONE TABOR CENTER 1200 17TH STREET, SUITE 1500 DENVER, CO 80202			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/642,440	Applicant(s) WALLACE ET AL.	
	Examiner Tamthom N. Truong	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1-17-06 (Election).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 25-36 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 25-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/12 + 4/2/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group 3 (claims 1-12 (in part)) in the reply filed on 1-17-06 is acknowledged. The traversal is on the ground(s) that "it would not be undue burden for the examiner to search both aryl and heteroaryl groups during his search of 544". This is not found persuasive because the search for quinazoline ring with R¹ as either an aryl or heteroaryl group would yield a total of 6,165 hits as stated in the reasoning of the restriction requirement. Furthermore, quinazoline compounds with R¹ as an aryl group is patentably distinct from those with R¹ as a heteroaryl group.

The requirement is still deemed proper and is therefore made FINAL.

The election of species in Example 45 is also acknowledged.

Claims 13-24 have been withdrawn from consideration as being drawn to the non-elected subject matter.

Claims 25-36 have been added.

Claims 1-12 and 25-36 are pending.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-12 and 25-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claims 1 and 9 recite the limitation of “*an R^4 group and an R^6 group may be independently joined to complete a 3 to 10 membered cyclic ring...*”, which has indefinite metes and bounds because it is unclear whether R^4 and R^6 must be connected to the same atom (e.g., $-NR^4R^6$), or they can be attached to different atoms (e.g., $-NR^4C(O)CR^6$) and still form a ring. In the case where there are two R^4 's (e.g., $-NR^4C(O)NR^4R^6$), it is unclear which of the R^4 could form a ring with R^6 , or if both could form a ring with R^6 to give a bicyclic heterocycle. Also, R^4 and R^6 appear in the definitions of A and R^3 , so it is unclear if the R^4 of A could form a ring with the R^6 of R^3 , which would fuse with the *quinazoline core* to give a tricyclic system.
- b. Claims 1 and 10 recite “*an R^6 group and an R^8 group may be independently joined to complete a 3 to 10 membered cyclic ring...*”, which has indefinite metes and bound because it is unclear if a *spiro cycle* is formed or a *ortho-fused* bicyclic system is formed. Furthermore, the definition of R^6 and R^8 is unclear because the moieties defined for those variables can also be substituted with OR^6 , or NR^6R^8 .
- c. Claims 1 and 11 recite “*an R^7 group and an R^8 group may be independently joined to complete a 3 to 10 membered cyclic ring...*”, which has indefinite metes and bound because it is unclear if a *spiro cycle* is formed or a *ortho-fused* bicyclic system is formed.
- d. Claims 1 and 12 recite “*an R^8 group and an R^9 group may be independently joined to complete a 3 to 10 membered cyclic ring...*”, which has indefinite metes and bound because it is unclear if a *spiro cycle* is formed or a *ortho-fused* bicyclic system is formed.

- e. Claim 1 also recites the limitation of “*solvates*” which has indefinite metes and bounds because it is unclear what solvent and its ratio are intended.
- f. The proviso for R⁶ in claim 1 is unclear because there is no instance where R⁶ is not directly bonded to Z. It appears that the proviso excludes hydrogen from the definition of R⁶ entirely.
- g. Claim 2 lacks antecedent basis because it depends on claim 1, but recites the limitation of “*wherein R² is a C₁₋₈ alkyl having a terminal carbon atom bound to one of the ring atoms of R¹*” which suggests a bicyclic system formed by R¹ and R², which is not recited in claim 1.
- h. Claims 2-12 and 25-35 are rejected as being dependent on claim 1, and carrying over the indefinite limitations.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-12 and 25-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10, 20-91 and 101-106 of copending Application No. 10/914,974 (Pregrant Publication No. US 2005/0043334 A1 or PP'334). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed formula I overlaps with formula I of PP'334 when their variables represent the following:

- i. A is Z (or $-(U)_nZ$; $n = 0$);
- ii. X is N;
- iii. R^1 is a substituted or unsubstituted, monocyclic or bicyclic, aryl moiety;
- iv. R^2 is H or a substituted or unsubstituted C_{1-8} alkyl;
- v. Z is the 5-membered ring having N, V and W single/double bonded to N;
- vi. V is CR^7R^8 or CR^8R^9 .

Species in claims 101-106 of PP'334 also anticipate the instantly claimed formula I, and are analogous to some species recited in the instant claim 36. Species in the instant claim 36 also anticipate formula I of PP'334.

Thus, it would have been within the level of the skilled chemist to select compounds of the instant formula I in view of formula I claimed in PP'334.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

References cited on PTO-892


References cited on PTO-892 only show state of the art. While they teach a quinazoline substituted with a group corresponding to Z, they fail to teach a substituent corresponding to – NR²(Aryl).

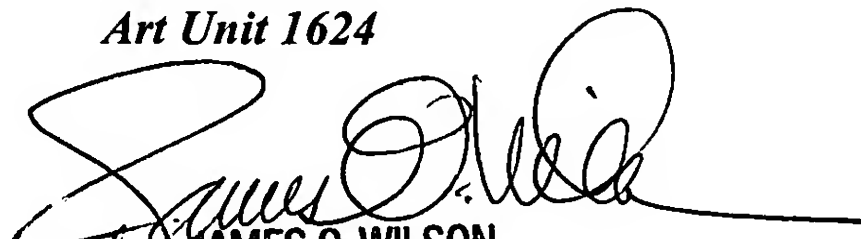
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3-1-06


Tamthom N. Truong
Examiner
Art Unit 1624


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